place the claims in condition for allowance. For at least the above reasons, it is submitted that claims 1-7, 9-17, 24 and 26-32 continue to be in a condition for allowance. The amendments do not introduce new issues, and entry thereof into the record is solicited.

Objections

Applicants continue to traverse the assertion of the lack of unity of invention. Nonetheless, in the interest of expediting prosecution, Claims 18-23 have been deleted.

Claim 24 has been rewritten in independent format and therefore obviates the Examiner's objection and claim 25 has been cancelled.

Rejections Under 35 U.S.C. § 112 ¶2

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

On pages 4-5, sections 3 and 4, claims 1-17, 26 and 27 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly containing subject matter which fails to particularly point out and distinctly claim the invention. Applicants continue to maintain that their claims, prior to this Amendment, were definite for all the reasons previously presented. Nonetheless, to expedite prosecution, in claim 1, the phrase "whereby the bacterial culture is not susceptible to attack by bacteriophages" was deleted. The claim now recites that "the metabolic activity of the bacterial culture is substantially unaffected by the bacteriophage" and the scope of claim 1 has remained substantially the same. The rejection is respectfully traversed..

35 U.S.C. § 112 ¶ 1

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

On pages 5-6, section 5, claims 1-3, 6-19, 21-27 and 30-32 stand rejected under 35 U.S.C. §112 ¶ 1, as the "specification does not provide adequate written description of the genus of bacterial cultures. The specification has provided only two species of the recited genus of bacterial cultures, i.e. a purine or a thymidine auxotrophic mutant bacterium, which is insufficient to provide description of the entire genus of recited bacterial cultures."

Applicants have amended claim 1 to recite the substrate being modified is milk. As such, the specification contains a written description (and enablement) for a broader scope of the

invention than is now claimed. Indeed, the claimed invention provides written description for a number of modified substrates including milk, a vegetable material, a meat product, a must, a fruit juice, a wine, a dough and a batter (page 10, lines 29-31) with any number of various bacteria, for example *Lactococcus* spp., *Lactobacillus* spp., *Leuconostoc* spp., *Pediococcus* spp., *Streptococcus* spp., *Propionibacterium* spp., *Bifidobacterium* spp., *Staphylococcus* spp., *Micrococcus* spp., *Bacillus* spp., *Enterobacteriaceae* spp. including *E. coli*, *Actinomycetes* spp., *Corynebacterium* spp. and *Brevibacterium* spp. (See, page 9, lines 2-7). The specification provides further written description of bacterial strains which can be used in the invention, e.g., page 18, lines 21-28, a number of substrates, e.g., page 10, lines 29-page 11, line 3 and a number of mechanisms, which can be used to provide a suitable bacteria or bacterial cultures, e.g., page 8, line 7-page 9, line 25. Applicants' specification, including the disclosure of a number of specific species provides a clear indication that Applicants, at the time their application was filed, possessed the subject matter of their entire claimed invention. This is particularly true as the invention is now directed to a specific substrate. Further, Applicants respectfully point out that the invention is directed to a method of modifying a bacterial culture in milk not a method of producing auxotrophic bacterial strains which is known in the art.

The rejection is respectfully traversed.

On pages 6-8, section 6 claims 1-17 and 24-32 stand rejected under 35 U.S.C. §112, ¶ 1a allegedly for failure to satisfy the enablement requirement. It was asserted that undue experimentation would be required to make the entire scope of the claimed invention. Applicants traverse this rejection. Applicants have provided a teaching which enables those skilled in the art to practice the entire scope of the claimed invention. Initially, Applicants again point out that the claims are now directed to milk as the substrate. Further, Applicants have disclosed a number of parameters for practicing their invention. Applicants have provided the disclosure of the properties of certain bacterial cultures, such as that of lactic acid bacterium, having an acidification rate in milk of at least 1% to at least 25% of the culture which, when it is present in a substrate material, is capable of DNA replication, RNA transcription and/or protein synthesis. (*See* page 10, lines 4-14). Applicants also provided a disclosure of concentration of the bacterial strain, e.g., 10^5 to 10^9 CFU/ml or g of the material. (*See* page 10, lines 16-21). Applicants additionally disclosed different types of non-proliferating cells which can be used, such as "resting cells" or "non-dividing cells". (*See, e.g.*, page 12, lines 11-17). Examples provide

additional detailed disclosure of some specific embodiments of the invention which further enhance the enabling nature of Applicants' general disclosure.

With regard to the development of auxotrophic bacterial strains, Applicants direct the Examiner's attention to page 8 lines 7-12, "[I]t will be appreciated that such auxotrophic bacteria can be provided by subjecting a wild type bacterial strain that, under appropriate conditions, is capable of growing in a substrate material with or without a specific compound needed for DNA replication, RNA transcription or protein synthesis to a mutagenization treatment and selecting a strain that is substantially incapable of growing in the absence of said specific compound." Further, [a]s an alternative, auxotrophic bacteria can be provided by selecting spontaneously occurring mutants which, compared to the parent strain, ha[s]ve a growth requirement for a compound needed for DNA replication, RNA transcription or protein synthesis." (page 8, lines 21-23). It should be noted that the invention is not directed to the development of auxotrophic strains, since methods for making the strains are known in the art and described in the present application. Rather the invention is directed to the recognition that auxotrophic bacterial strains may be used according to the methods of the claimed invention to retain metabolic activity of the bacterial culture or at least to have a substantially unaffected metabolic activity even if the milk is contaminated with bacteriophages. Further, Applicants have provided detailed examples of how one skilled in the art would practice the claimed invention. These examples utilize both purine and thymidine auxotrophic bacteria. As previously stated, in both the Response dated August 27, 2002 and the Declaration of Dan Nilsson, one skilled in the art would not need to engage in undue experimentation to practice the claimed invention. This is particularly true as the claims now recite the milk as the substrate.

The rejection is respectfully traversed.

Request for Allowance

All claims are in condition for allowance, an indication of which is solicited. In the event any outstanding issues remain, Applicants would appreciate a telephone call to their undersigned counsel to resolve such issues in an expeditious and effective manner.

It is believed that no fees are due in connection with this Amendment. However, if any additional fees are determined to be due, the Director is hereby authorized to charge such fees to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS

Dated: April 8, 2003

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